



# **Study Drug**

**Study AC-060A202: CONTROL**  
**Laura Alberti**



## Study Drug

Randomization ratio 1:1:1:1

4 Arms:

- A: ACT-129968 1000mg bid
- B: ACT-129968 500mg bid
- C: ACT-129968 100mg bid
- D: Placebo bid

**Reliever**  
**SABA as needed**

Salbutamol/albuterol provided as reliever medication including  
Spacer

## Study Drug

- ACT-129968 (double blind, dummy via IVRS/IWRS)
- Twice daily (bid)
- 1 Dose = 4 Capsules
- 100mg/250 mg/Placebo Capsules



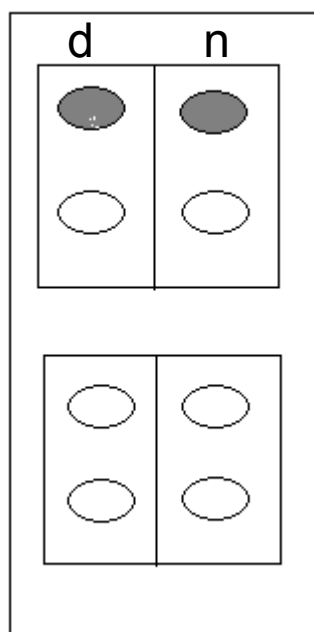
## AC-060A202 CONTROL: Packaging

- 1 Blister per day
- 7 Blisters per kit
- 1 Kit per week
- Demo kit for SIV

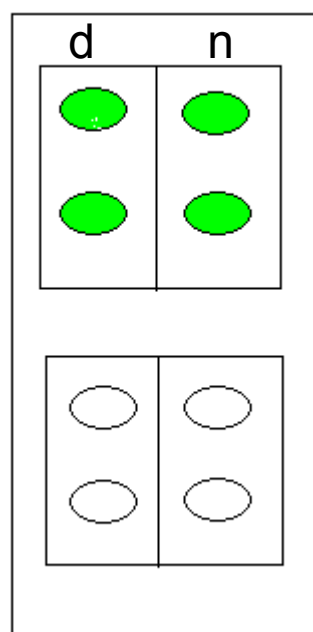


# Packaging

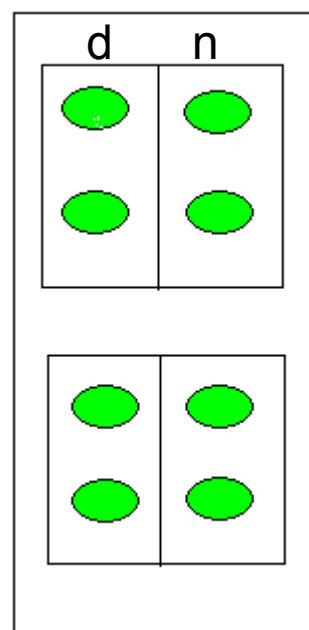
4 different blister cards



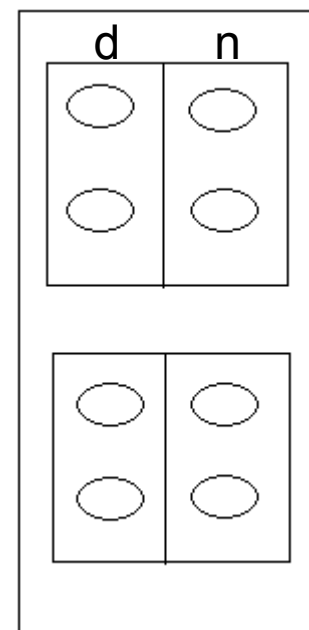
**100mg bid**



**500mg bid**

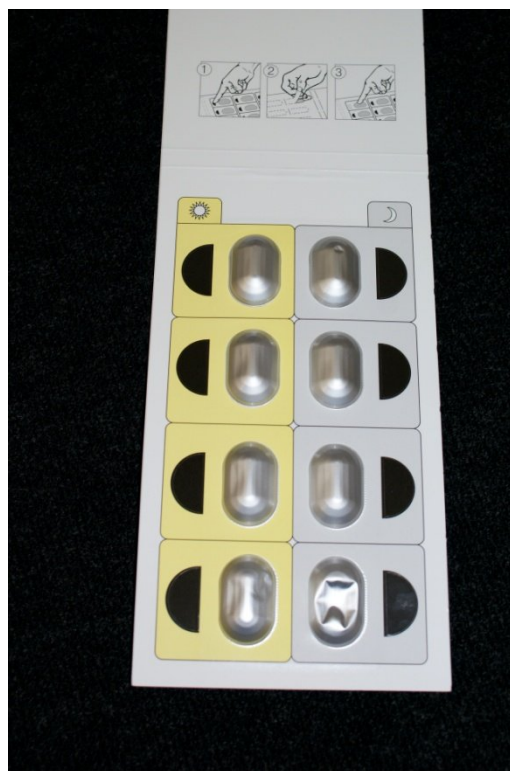


**1000mg bid**



**Placebo**

## Packaging

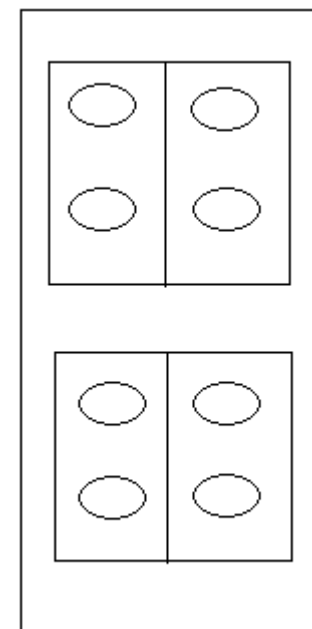


## AC-060A202 CONTROL: Packaging



## AC-060A202 CONTROL: Swallow Test

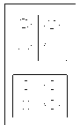


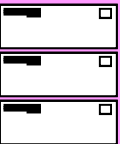
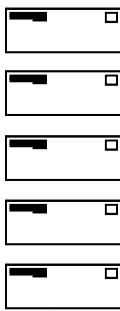
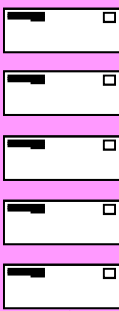
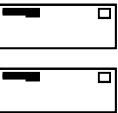
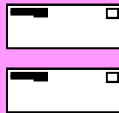
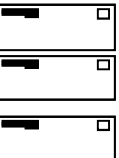
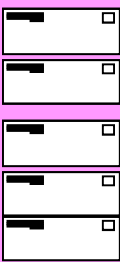
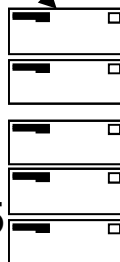
- At screening
- 4 placebo capsules to be taken
- PI MUST offer swallow test to subject at screening



**Swallow test  
blister**



## Study Drug Schedule

	Scr.	Rand.	W1	W2	W4	W8	W12	W14
	V1	V2	V3	V4	V5	V6	V7 EOT	V8 EOS
Kit Dispensation	Swallow test 							
Total kits dispensed		2	2	3	5	5	0	0
Kits returned			 2	 2	 3	 5	 5	

## Reliever Therapy

- Salbutamol /Albuterol in pressurized metered dose inhaler (Spray)
- Spacer provided with Salbutamol/Albuterol
- Will be given to each patient by Investigator at Visit 1 (Screening)
- Replacement of previously used reliever therapy
- Use as needed



## Initial Shipment

- Upon site activation each site will receive:
  - 12 kits of IMP (3 kits per Treatment arm)
  - OR
  - 20 kits of IMP (5 kits per Treatment arm if PK-CM sub-study site)
  - AND
  - 5 kits of Swallow-test blisters
  - 20 salbutamol inhalers
  - 12 spacers

## Storage

- Stored in locked and secure area with limited access
- Kept at ambient temperature (<25 °C)
- Protected from moisture and heat source
- Salbutamol /albuterol stored according to manufacturer's guidelines

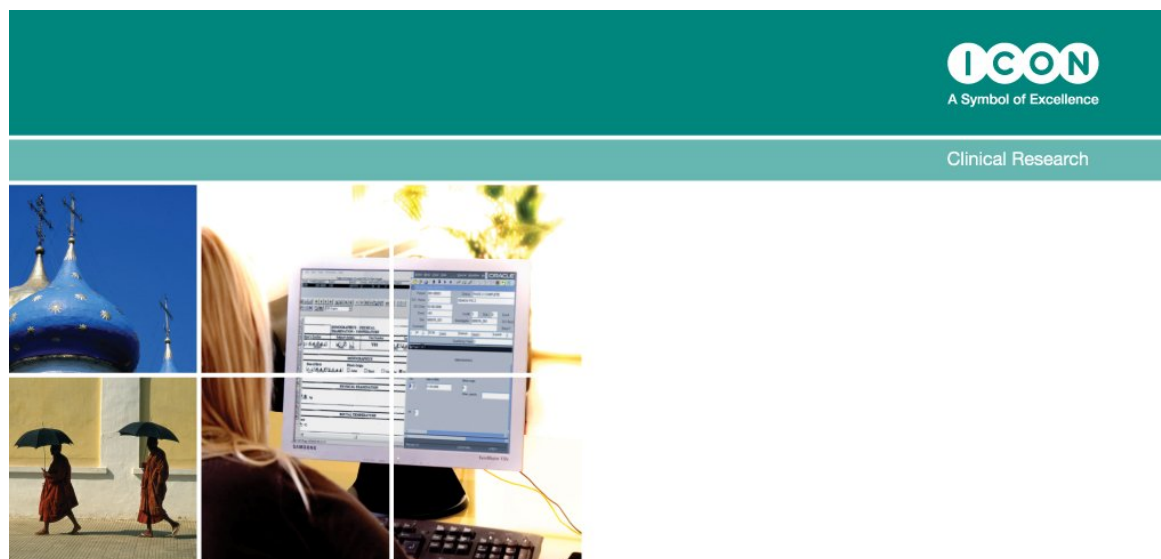
## Depots

- Central depot Almac UK :  
Bulgaria, Germany, Hungary, Poland, Serbia
- Local Almac depots:  
Australia, Israel, Singapore, South-Africa, Sweden and US
- Local PSI depots:  
Russia and Ukraine

## Site Activation

- First drug supply from central/local depot to site will be arranged by Actelion
- Receipt of drug shipment by site needs to be confirmed into the system upon reception
- Site will be activated in the system after SIV conducted
- Stock levels will be monitored nightly
- Resupply shipments will be triggered by ICOPhone system

## Handling of IMP



## ICON Interactive Technologies

## **ICOPhone & ICOWeb *System Modules***

- Screening
- Screen Fail
- Randomization
- Subject Resupply
- Emergency Resupply
- Emergency Unblinding
- Replace Treatment
- Confirm Shipment
- End of Treatment / Discontinuation
- End of Study/Completion of a subject
- Medications Return for Site (CRA only)



## **Accessing ICOPhone**

**Enter the system by:**

- **Toll-free Telephone number**
- OR**
- **Log on to [www.ICOPhone.com](http://www.ICOPhone.com)**

**Enter your unique User ID**

**Enter your unique PIN**

**Log-in information will be sent via email prior to SIV**

## Accessing ICOPhone

<b>Welcome Menu</b>		
<b>Main Menu</b>	<b>1</b>	<b>Register a subject visit</b>
	<b>2</b>	<b>Replace a treatment kit</b>
	<b>3</b>	<b>Confirm receipt of a drug shipment</b>
	<b>4</b>	<b>Unblind a subject</b>
	<b>5</b>	<b>Repeat the menu choice</b>
	<b>9</b>	<b>Exit Menu</b>

## Subject processing Calls

	Screening	Screen Fail	Randomization
System collects	<ul style="list-style-type: none"> <li>✓ Date of Birth</li> <li>✓ Gender</li> <li>✓ Visit date</li> </ul>	<ul style="list-style-type: none"> <li>✓ Subject Number</li> <li>✓ Date of Birth</li> <li>✓ Screen Fail Date</li> <li>✓ Screen Fail Reason</li> </ul>	<ul style="list-style-type: none"> <li>✓ Subject Number</li> <li>✓ Date of Birth</li> <li>✓ Site participation in the PK-CM Sub Study</li> <li>✓ Subject participation in the PK-CM Sub Study</li> </ul>
System Provides	<ul style="list-style-type: none"> <li><input type="checkbox"/> Subject Number</li> <li><input type="checkbox"/> Confirmation Document</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Confirmation Document</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Randomization Number</li> <li><input type="checkbox"/> Kit Number</li> <li><input type="checkbox"/> Confirmation Document</li> </ul>

**Both to be entered in CRF**

## Drug Dispensing Calls

	Resupply	Treatment Replacement
System collects	<ul style="list-style-type: none"> <li>✓ Subject Number</li> <li>✓ Date of Birth</li> <li>✓ Visit Number</li> </ul>	<ul style="list-style-type: none"> <li>✓ Subject Number</li> <li>✓ Date of Birth</li> <li>✓ Kit to be Replaced</li> </ul>
System Provides	<ul style="list-style-type: none"> <li><input type="checkbox"/> Kit Number</li> <li><input type="checkbox"/> Confirmation Document</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Replacement Kit Number</li> <li><input type="checkbox"/> Confirmation Document</li> </ul>

## Non- Dispensing Calls

	End of Study / End of Treatment
<b>System collects</b>	<ul style="list-style-type: none"><li>✓ Subject Number</li><li>✓ Date of Birth</li><li>✓ End of Study Date</li></ul>
<b>System Provides</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Confirmation Document</li></ul>

## Emergency Unblinding Call

**This Option is available to Principal Investigator at Site ONLY!**

<b>System collects</b>	<ul style="list-style-type: none"><li>✓ Subject Number</li><li>✓ Date of Birth</li></ul>
<b>System Provides</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Kit assignment (Drug Description)</li><li><input type="checkbox"/> Confirmation Document</li></ul>

## Web Report – Log on Page

- Go to [www.ICOPhone.com](http://www.ICOPhone.com)



About UsDemoSupportContact

**Login** ?

UserID

PIN  **Login**

### Welcome to ICOPhone™ Portal

Participants in projects managed by ICON can use this secure interactive service to view current project information. To access project information, enter your UserID (assigned by ICON) and your PIN (Personal Identification Number). If you have lost or have not been assigned a UserID, you can request to have it sent to you by calling **ICON Technical Support**.

To protect the system from unauthorized use and to ensure that the system is functioning properly, activities on this system are monitored and recorded and subject to audit. Use of this system is expressed consent to such monitoring and recording. Any unauthorized access or use of this automated information system is prohibited and could be subject to criminal and civil penalties.



23AC-060A202: CONTROL – Study DrugInvestigators Meeting, Barcelona – 20 & 21 January 2011


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## Web Reports for Investigator Sites

- You will have access to the following Reports:
  - Shipment Summary
  - Screening Report
  - Screen Fail Report
  - Randomization Report
  - End of Treatment/Discontinuation Report
  - Visit Summary
  - Site Drug Inventory- Blinded



# Screen Fail Report – AC-060A202 Example


Christopher Able
Sep 16 2009
11:31:44 AM CST
Development

[Main](#)
[Helpcenter](#)
[Search](#)
[Guidelines](#)
[Logout](#)

## Screen Fail Report

Open this report in Excel: Formatted or Raw

All |  |

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Viewing Records 1 to 4 out of 4 total records.

Subject Number	DOB	Visit Date	Gender	Screenfail Reason	Confirmation (doc)
Site: 1212 [Inv, First]					
10002	Jan 01 1955	Aug 12 2009	MALE	Reversibility of the airway obstruction not demonstrated, ACQ < 1.5	1267101
10005	Jan 01 1989	Aug 14 2009	FEMALE	Other	1262532
10006	Jan 01 1988	Aug 11 2009	FEMALE	Other, ACQ < 1.5, Ongoing or recent treatment with medication for allergic airways disease	1261154
10007	Jan 01 1955	Aug 14 2009	Female	Patient consent withdrawal	1262534

**Total number of Records found:** 4

**Total number of Sites found:** 1

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 Investigators Meeting, Barcelona - 2008-21 January 2010 AM
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## Help Desk

- 24 hours per day, 7 days per week
- Email access & toll-free phone access
- 140 languages supported
- Trained on system & protocol
- Toll Free Number: 00 888 426 8801 or [icophone@iconus.com](mailto:icophone@iconus.com)

## Accessing the ICOPhone HelpDesk

- User support is available 24 hours/day, 7 days/week.
- The Help Desk's toll-free telephone number and email address is printed on all site instructions and confirmation faxes:
  - Toll-free numbers are specific per country
  - [icophone@iconus.com](mailto:icophone@iconus.com) (only use for non-urgent inquiries)
- The Help Desk is available in all languages!
- When calling or logging on, please be prepared to provide your ICON User ID.

## Demonstration

ICOWeb Demo  
[www.icophone.com](http://www.icophone.com)

Enter User ID 10000  
Pin 9999

ICOPhone Demo  
+1.800.594.4977

Enter User ID 10000 Pin  
9999

## Accessing ICOPhone Practice System

- To enter the practice system follow the same steps as before. However, instead of entering your “live PIN” please enter your Practice PIN “0000”
- The following Options are available in Practice Mode:
  - For Investigators
    - Screening Call
    - Randomization Call
  - Coordinators:
    - Screening Call
    - Randomization Call
  - For All other Users
    - No Practice Option available



**Thank You!**

